

3971. Misbranding of Metandren tablets, Amytal Sodium capsules, and Pentresamide tablets. U. S. v. King Cut Rate Drugs, Inc., and Joe Goldberg. Plea of nolo contendere by corporation and plea of guilty by individual. Fine of \$250 against corporation and \$500 against individual. (F. D. C. No. 34350. Sample Nos. 34361-L, 34368-L, 34800-L.)

INFORMATION FILED: March 19, 1953, Southern District of Illinois, against King Cut Rate Drugs, Inc., Quincy, Ill., and Joe Goldberg, president of the corporation.

ALLEGED VIOLATION: On or about March 13 and 19, 1952, while a number of *Metandren tablets*, *Amytal Sodium capsules*, and *Pentresamide tablets* were being held for sale at King Cut Rate Drugs, Inc., after shipment in interstate commerce, the defendants caused various quantities of the drugs to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (d), the repackaged *Amytal Sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the repackaged capsules failed to bear a label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (2), the repackaged *Pentresamide tablets* failed to bear a label containing the common or usual name of each active ingredient of the tablets.

DISPOSITION: April 16, 1953. A plea of nolo contendere having been entered by the corporation and a plea of guilty by the individual, the court fined the corporation \$250 and the individual \$500.

3972. Misbranding of Femo tablets and Femo pills. U. S. v. 24,000 Tablets, etc. (F. D. C. No. 31325. Sample Nos. 11176-L, 11177-L.)

LABEL FILED: July 9, 1951, Northern District of Ohio.

ALLEGED SHIPMENT: On or about January 19 and 30 and May 25, 1951, by the Chicago Pharmacal Co., from Chicago, Ill.

PRODUCT: 24,000 *Femo tablets* and 12,000 *Femo pills*, together with an unknown number of labels intended for use upon the articles when repackaged, in the possession of the Lipton Drug Sales Co., Cleveland, Ohio. The tablets had been shipped in interstate commerce in drums, and the pills had been shipped in bottles. Portions of both products had been repacked by the consignee, the Lipton Drug Sales Co., into cartons, each containing 24 tablets or pills.

LABEL, IN PART: (Drums in which tablets were shipped) "Ergot, Aloin and Cotton Root Bark Compound No. 2 * * * Ergot Extract 0.5 gr Aloin 0.125 gr Cotton Root Bark Extract 0.5 gr Apiol 0.25 min Oil Pennyroyal 0.01 min Caution: To be dispensed only by or on the prescription of a physician. Warning: For temporary use only and as needed; and not for habitual use. Warning: Ergot is contraindicated in pregnancy, high blood pressure, vascular disease, coronary sclerosis and puerperal infection."

(Bottles in which pills were shipped) "Ergot Cotton Root Bark and Apiol Compound * * * Ergot $\frac{1}{2}$ gr Warning: Ergot is contraindicated in pregnancy, high blood pressure, vascular disease, coronary sclerosis and puerperal infection. Ext. Cotton Root Bark $\frac{1}{2}$ gr Apiol $\frac{1}{4}$ min Pulsatilla $\frac{1}{4}$ gr Oil Pennyroyal $\frac{1}{10}$ min Caution: To be dispensed only by or on the prescription of a physician."

(Cartons containing tablets) "Femo Pills Special formula containing the Emmenagogues Ergot, Aloin, Extract of Cotton Root Bark, Apiol, and Oil Pennyroyal (Adult Use Only) Directions: 1 capsule after meals and at bedtime. Contents 24 Capsules * * * To be used only by or on the prescription of a Physician."

(Cartons containing pills) "Super Femo Pills Original formula containing the Emmenagogues Extract Ergot, Extract Cotton Root Bark, Apiol, Pulsatilla, and Oil of Pennyroyal (Adult Use Only) Directions: 1 capsule after meals and 1 at bedtime. Contents 24 Pills * * * To be used only by or on the prescription of a physician."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the tablets and pills failed to bear adequate directions for use. The articles were misbranded in this respect when introduced into, while in, and while held for sale after shipment in, interstate commerce.

Further misbranding, Section 502 (a), the statement "containing * * * Emmenagogues" borne on the cartons containing the repackaged tablets and pills was false and misleading since the articles, when used as directed, were not effective as emmenagogues. The articles, were misbranded in this respect while held for sale after shipment in interstate commerce.

DISPOSITION: January 27, 1953. The Lipton Drug Sales Co. having filed an answer to the libel, but subsequently having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the products be destroyed.

3973. Misbranding of Cheno herb tea laxative, Cheno preparation of Phytolacca berries, and Cheno combination tablets. U. S. v. 26 Cartons, etc. (F. D. C. No. 18986. Sample Nos. 36073-H to 36075-H, incl.)

LIBEL FILED: January 21, 1946, Western District of Oklahoma; amended on or about March 14, 1947.

ALLEGED SHIPMENT: In September, November, and December, 1945, and on or about January 14, 1946, by the Alberty Food Products Co., from Hollywood, Calif.

PRODUCT: 26 cartons of *Cheno herb tea laxative*, 24 bottles of *Cheno preparation of Phytolacca berries*, and 8½ dozen cartons of *Cheno combination tablets* at Oklahoma City, Okla.

LABEL, IN PART: "Cheno Herb Tea Laxative Contains: Active laxative ingredient Senna * * * Dosage: Depends upon the individual. Use from one to three teaspoonfuls. Make tea by boiling herbs in a cupful of water. Remove from fire, cover and let steep fifteen minutes or all day; strain before drinking * * * Use as occasionally required for relief of temporary constipation," "Cheno Preparation of Phytolacca Berries * * * App. 50% of Liquid Berry Juice * * * Directions: 6 drops, 3 times daily 15 minutes before each meal in one-half glass of water," and "10 Grain Cheno Combination Tablets * * * Directions: Four tablets before meals, as a supplementary Food source of Calcium, Phosphorus, Iron and Iodine. Cheno